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Ortho Molecular Products Inc. 3017 Business Park Drive P.O. Box 1060 Stevens Point, WI 54481 715 342.9881 Phone 800 332.2351 715.342.9866 Fax orthomolecular products.com Office of Special Nutritional (HFS-450)
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

MAY 25 2014

## Dear Sir/Madam:

This letter will serve as notification, pursuant to section 403 (r)(6) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 101.93, that Ortho Molecular Products, Inc. is using the following claim on its label (see attached labels on page 2).

Name of Manufacturer: Ortho Molecular Products, Inc.

3017 Business Park Drive

P.O. Box 1060

Stevens Point, WI 54481

Statement Text: Muscular / Skeletal Health

Dietary Ingredients: Glucosamine Sulfate, Natural vegetable capsules, Ascorbyl Palmitate, Magnesium Stearate, Microcrystalline Cellulose, Silicon Dioxide.

Dietary Supplement Name: Glucosamine Sulfate

As required, enclosed are two photocopies of this notification.

I certify that the information presented and contained in this notice is complete and accurate, and that Ortho Molecular Products, Inc. has substantiation that the statement is truthful and not misleading.

Sincerely,

Melissa Slager

Document Control / Training Manager

Mussa Slaser

Ortho Molecular Products

975 0162 LET 16247



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## Attachment of Glucosamine Sulfate Labels

Suggested Use: As a dietary supplement, 1 capsule two times per day or as suggested by your health care professional.
Formulated to be free of allergens derived from: Gluten, corn, egg, dairy, peanuts, soy, yeast, artificial colors and flavors. If you are pregnant or nursing, consult your physician before taking this product. As with all dietary supplements, some individuals may not tolerate or may be allergic to the ingredients used. Please read the ingredient panel carefully prior to ingestion. Cease taking this product and consult your physician if you have negative reactions upon ingestion. Keep container tightly glosed. Store at room TEMPERATURE. KEEP OUT OF REACH OF CHILDREN.

† These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.



Label ID L-OMP100-541060-C



Glucosamine Sulfate

Supplement Facts
Serving Size 1 Capsule

Servings Per Container: 60

Amount Per % Daily

Serving 1 capsule contains Glucosamine Sulfate 750 mg

\* % Daily Value not established

Other ingredients: Natural venetable capsules. This product may contain one or more of the Tollowing: Ascorbyl Palmilate, Magnasium Stearate, Microcrystalline Cellulose and Silicon Dioxide

Tins product was sealed for your protection. Do not use if outer logged neck seal or inner-seal are missing or damaged.

Mile: by: Orthe Molecular Products, Inc. 3017 Business Park Orive Stevens Point, Wi. 5448: OrthoMelecularProducts.com

Suggested Use: As a dietary supplement, 1 capsule two times per day or as suggested by your health care professional. Formulated to be free of allergens derived from. Gluten, corn, egg, dairy, peanuts, soy, yeast, artificial colors and flavors. If you are pregnant or nursing, consult your physician before taking this product. As with all dietary supplements, some individuals may not tolerate or may be allergic to the ingredients used Please read the ingredient panel carefully prior to ingestion. Cease taking this product and consult your physician if you have negative reactions upon ingestion. KEEP CONTAINER TIGHTLY CLOSED STORE AT ROOM TEMPERATURE. KEEP OUT OF REACH OF CHILDREN: † These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

Label ID L-OMP100-541120-C

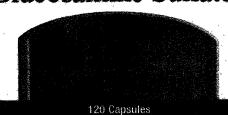




Dietary Supplement Product #541A

**PRODUCTS** Because Efficacy Matters®

## Glucosamine Sulfate



Supplement Facts Serving Size 1 Capsule

Servings Per Container: 120

Amount Per % Daily 1 capsule contains Serving Value

Glucosamine Sulfate 750 mg

% Daily Value not established

Other ingredients: Natural vegetable capsules. This product may contain one or more of the following: Ascorbyl Palimitate, Magnesium Stearate, Microcrystalline Cellulose and Silicon Dioxide.

This product was sealed for your protection. Do not use if outer logoed neck seal or inner-seal are missing or damaged

Mfg, by Ortho Molecular Products, Inc. 3017 Business Park Drive Stevens Point, WI 54481